K022865

Demand Oxygen Conserving Device
510(k) Summary

FEB 1 3 2003

Submitter's Name, Address, Telephone Number and Contact Person

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Date Prepared

August 27, 2002

Name of Device

Trade Name:	6203
Common Name:	Oxygen Conserver
Classification Name:	Ventilator, Non-Continuous (Respirator) 21CFR 868.5905
Product Code:	73 NFB

Predicate Device

Contemporary Products, Inc., OCD2001 (K992935)

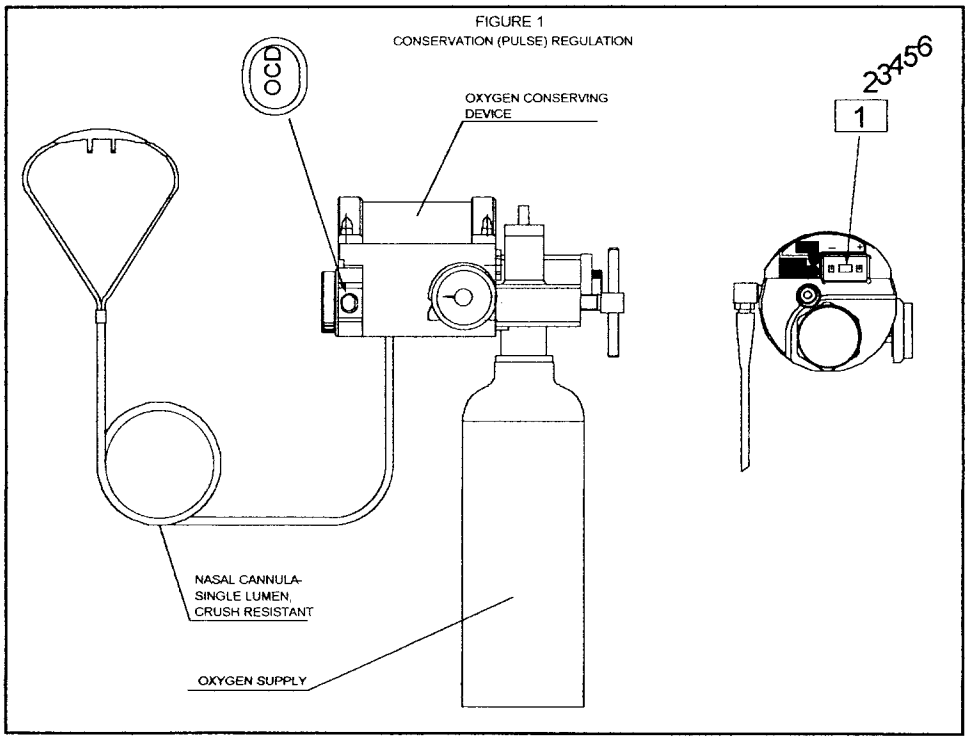
Intended Use

The 6203 is indicated for use to conserve oxygen for patients prescribed 1 to 6 liters per minute of supplemental oxygen and use nasal cannulas and USP bottled oxygen.

Technological Characteristics and Substantial Equivalence

The 6203 with integrated pressure regulator is intended to be used as an accessory to an oxygen supply system to reduce or conserve the amount of oxygen used by the patient. The 6203 is a battery operated electronic device that is microprocessor controlled and contains a breath sensor and a normally closed valve. When installed between the oxygen supply and patient's nasal cannula, the device detects the patient's inhalation, opens the valve according to the flow rate set on the device and delivers a preset bolus of oxygen to the patient as determined by the device flow rate algorithm. The valve closes and conserves the oxygen that would have been wasted during the end of inhalation and during exhalation.

The 6203 is intended to be used with USP bottled oxygen and nasal cannulas and is installed as shown in the following figure:



The side panel of the 6203 has a selector switch, battery status light and flow fault/apnea light. The battery LED winks every two (2) seconds when about 3 hours remain in the batteries and once every second when about 30 minutes

remain. It then lights steady if batteries can no longer properly power the unit informing the patient that the unit has shut down.

When the selector switch is set to "ON" the device operates as follows:

The sensing diaphragm closes its circuit in response to .5cm negative pressure produced by the user's inhalation effort. This circuit closing is input into the microprocessor. The microprocessor then opens the valve to allow the appropriate bolus of oxygen to flow (based upon the chart that follows) and then waits for the next negative pressure.

Chart 1

Liter Flow Setting	Bolus Size
1 lpm	15 ml
2 lpm	28 ml
3 lpm	41 ml
4 lpm	55 ml
5 lpm	68 ml
6 lpm	81 ml

The 6203 contains an alarm package that is designed to alert the user in the event of disconnection of the cannula or unit malfunction. The 6203 will produce an audible alarm tone to alert the user if it has not detected sufficient negative pressure to close the circuit on the sensing diaphragm within 45 seconds. The 6203 will cause the flow/apnea light to light a steady red if the microprocessor should fail.

The 6203 is substantially equivalent in intended use and principal of operation to other oxygen conserving devices including our own device, the OCD2001 referenced above (K992935 now marketed as the 6200); the Invacare IPD Oxygen Conserving Device (K953852) and the Chad Therapeutics Oxymatic Electronic Oxygen Conserver (K852650). These predicate devices, like the 6203, are electronic products that use a breath sensor and normally closed valve. Additionally, the Invacare IPD Oxygen Conserving Device, like the 6203 opens the valve and delivers the oxygen to the patient on every detected inhalation.

Performance Data

Extensive functional testing of the 6203 has been performed. In addition, testing of the device has been performed under various environmental conditions, including impact/drop testing, storage temperature testing, electromagnetic interference testing, electrostatic discharge testing and surface temperature testing. Power supply testing was also performed; these tests included battery life testing and low power indicator testing. The functional, environmental and power supply testing performed on the device demonstrated that it meets its performance objectives and complies with applicable FDA guidelines.

The electronic components and software design are identical to the Contemporary Products, Inc. predicate device, OCD2001 (6200).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2003

Mr. Barry A. Schwartz
President
Contemporary Products, Incorporated
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Portland, Maine 04103

Re: K022865
Trade/Device Name: 6203 Demand Oxygen Conservation Device
Regulation Number: 21 CFR 868.5905
Regulation Name: Oxygen Conserver
Regulatory Class: II
Product Code: 73 NFB
Dated: December 3, 2002
Received: December 4, 2002

Dear Mr. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Contemporary Products, Inc.

Wave Conserver Model 6203

Indications for Use Statement

510(k) Reference Number: K022865

This is an initial submission; no number has yet been assigned

Statement of Indications for Use:

The Wave Conserver Model 6203 is indicated for use to conserve oxygen for patients prescribed 1 to 6 liters per minute of supplemental oxygen and use of a nasal cannula and USP bottled oxygen.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)

Division of Cardiovascular, Respiratory and Neurological Devices

510(k) Number:

Prescription Use ✓ OR Over-the Counter Use _____

(Per 21 CFR 801.109)

2/12/03

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022865